BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2017-0015, NIOSH-295]

Health Risks to Workers Associated with Occupational Exposures to Peracetic Acid; Request for Information

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention intends to evaluate the scientific and technical data on occupational exposures to peracetic acid (CAS # 79-21-0, also known as peroxyacetic acid and PAA). NIOSH is requesting information on the following: (1) workplace exposure data for peracetic acid, (2) possible health effects observed in workers exposed to peracetic acid, (3) workplaces and products in which peracetic acid may be found, (4) description of work tasks and scenarios with a potential for exposure to peracetic acid, (5) reports and

findings from in vitro and in vivo toxicity studies with peracetic acid, (6) data applicable to the quantitative risk assessment of health effects associated with acute, subchronic and chronic workplace exposures to peracetic acid, (7) sampling and analytical methods for peracetic acid, and (8) control measures, including engineering controls, work practices, and personal protective equipment (PPE), that are being used in workplaces where there is potential for exposure to peracetic acid.

DATES: Electronic or written comments must be received by
[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]

ADDRESSES: You may submit comments, identified by CDC-2017-0015 and docket number NIOSH-295, by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov
 Follow the instructions for submitting comments.
- Mail: National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2017-0015; NIOSH-295]. All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: G. Scott Dotson, NIOSH,

Education and Information Division, Robert A. Taft Laboratories,

1090 Tusculum Avenue, Cincinnati, OH 45226, (513) 533-8540 (not
a toll free number).

SUPPLEMENTARY INFORMATION: Peracetic acid is a peroxide-based molecule used extensively as an antimicrobial agent in many commercial applications. It is routinely used as a sterilant during the cleaning of endoscopes and other medical devices, as a disinfectant in food processing, as a bleaching agent, and in the synthesis of other chemicals [NAS 2010; Pechacek et al. 2015]. The chemical and physical properties of peracetic acid make the molecule highly reactive, unstable, and volatile. Peracetic acid has a pungent, vinegar-like odor [NAS 2010].

Peracetic acid is formed from a sulfuric acid-catalyzed chemical reaction between acetic acid and hydrogen peroxide [NAS 2010]. Peracetic acid solutions typically consist of a mixture of peracetic acid, acetic acid, and hydrogen peroxide in various concentrations. NAS [2010] reported that technical or commercial peracetic acid products contain peracetic acid, acetic acid, and hydrogen peroxide in solution. Concentrations of peracetic acid in these products vary, but do not exceed 40%. Peracetic acid products containing more than 15% peracetic acid demonstrate excessive reactivity, instability, and some degree of explosiveness [Pechacek et al. 2015].

Acute exposure to peracetic acid is irritating to the eyes, respiratory tract, and skin. Peracetic acid is a strong sensory irritant considered to be more potent than acetic acid or hydrogen peroxide [NAS 2010]. Cristofari-Margquand et al. [2007] indicated that healthcare workers experienced asthma associated with workplace exposures to peracetic acid. No data on human lethality due to exposure to peracetic acid were identified. Lethal exposures in animals caused hemorrhage, edema, and pulmonary consolidation [NAS 2010].

NIOSH does not have a recommended exposure limit (REL) for peracetic acid. The Occupational Safety and Health

Administration (OSHA) has not established a permissible exposure limit (PEL). The California Division of Occupational Safety and Health (CalOSHA) has not established a PEL for peracetic acid. The American Conference of Governmental Industrial Hygienists (ACGIH®) has established a threshold limit value (TLV®) - short term exposure limit (STEL) of 1.24 mg/m³ (0.4 ppm) to protect workers against irritation of eyes, skin, and the upper respiratory tract [ACGIH® 2016]. The National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) has established AEGL values for peracetic acid [NAS 2010]. AEGL values are threshold exposure limits for the general public and are applicable to emergency exposure periods ranging from 10 minutes to 8 hours [NAS 2001]. AEGL-1 represents an airborne concentration above which exposures could cause notable discomfort, irritation, or certain asymptomatic non-sensory effects. AEGL-2 represents an airborne concentration above which exposures could cause irreversible or other serious, long lasting adverse effects or an impaired ability to escape. AEGL-3 represents an airborne concentration above which exposures could cause life-threatening effects or death. Table 1 summarizes the AEGL values for peracetic acid.

Table 1 - AEGL Values for Peracetic Acid*

	10 minute	30 minute	60 minute	4 hour	8 hour
AEGL-1	0.52 mg/m^3				
	(0.17 ppm)				
AEGL-2	1.6 mg/m^3	1.6 mg/m^3	1.6 mg/m^3	1.6 mg/m^3	1.6 mg/m ³
	(0.5 ppm)				
AEGL-3	60 mg/m ³	30 mg/m^3	15 mg/m^3	6.3 mg/m ³	4.1 mg/m ³
	(19 ppm)	(9.6 ppm)	(4.8 ppm)	(2 ppm)	(1.3 ppm)

^{*}NAS [2010]

In May 2015, NIOSH published a notice in the Federal Register [80 FR 24930] announcing the availability of and a request for comments for the draft immediately dangerous to life or health (IDLH) values and support technical documents, entitled Immediately Dangerous to Life or Health (IDLH) Value Profiles, for 14 chemicals including peracetic acid. The proposed IDLH value for peracetic acid was 1.7 mg/m^3 (0.55 ppm) [draft NIOSH 2015]. The proposed recommendation was based on sensory irritation in human volunteers reported in Fraser and Thorbinson [1986]. Due to subsequent requests from the public, a supplemental notice was published in the Federal Register [81 FR 53147] announcing that NIOSH was seeking further comments on the draft IDLH Value Profile for peracetic acid. The public comments indicated that 1) the proposed IDLH value was overprotective, 2) the data available for peracetic acid are of low quality, and 3)

issues exist with the sampling and analysis of air samples for peracetic acid in the workplace. Based on these comments, NIOSH is re-evaluating the proposed IDLH value for peracetic acid.

Research efforts are needed to characterize the acute and chronic health effects of occupational exposures to peracetic acid. These efforts include: 1) epidemiological and field studies designed to assess workplace exposures to peracetic acid, 2) in vivo and in vitro studies designed to characterize the acute, sub-chronic, and chronic effects of peracetic acid, 3) quantitative risk assessment(s) intended to characterize the increased risks associated with workplace exposures to peracetic acid, 4) evaluation of workplace controls, including engineering controls, administrative controls, and PPE, 5) development of analytical methods to accurately collect and analyze air samples of peracetic acid under various conditions (e.g., task-based monitoring, full-shift monitoring, real-time monitoring).

Background: The purpose of the RFI is to seek information relevant to assessing the risk of occupational exposures to peracetic acid.

Information Needs: Additional data and information are needed to assist NIOSH in characterizing and assessing the health risk of

occupational exposures to peracetic acid. Information is needed on: (1) workplace exposure data for peracetic acid, (2) possible health effects observed in workers exposed to peracetic acid, (3) workplaces and products in which peracetic acid may be found, (4) description of work tasks and scenarios with a potential for exposure to peracetic acid, (5) reports and findings from in vitro and in vivo toxicity studies with peracetic acid, (6) data applicable to the quantitative risk assessment of health effects associated with acute, subchronic and chronic workplace exposures to peracetic acid, (7) sampling and analytical methods for peracetic acid, and (8) control measures, including engineering controls, work practices, and personal protective equipment (PPE), that are being used in workplaces where there is potential for exposure to peracetic acid.

References:

ACGIH® (American Conference of Governmental Industrial Hygienists) [2016]. Annual TLVs® (Threshold Limit 4 Values) and BEIs® (Biological Exposure Indices) booklet. Cincinnati, OH: ACGIH® Signature Publications.

Cristofari-Marquand E, Kacel M, Milhe F, Magnan A, Lehucher-Michel MP [2007]. Asthma caused by peracetic acid-hydrogen peroxide mixture. J Occup Health 49(2):155-158.

Fraser JAL, Thorbinson A [1986]. Fogging trials with Tenneco Organics Limited (30th June, 1986) at Collards Farm. Solvay Interox. Warington, United Kingdom.

NAS (National Academies of Science) [2001]. Standing operating procedures for developing acute exposure guidelines levels for hazardous chemicals. Washington, DC: National Academy Press.

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NAS [2010]. Chapter 7: peracetic acid-acute exposure guideline levels. In: acute exposure guideline levels for selected airborne chemicals: volume 8.

[http://www.epa.gov/opptintr/aegl/pubs/peracetic_acid_final_volu me8 2010.pdf].

NIOSH (National Institute for Occupational Safety and Health)
[draft 2015]. Immediately dangerous to life or health (IDLH)
value profile for peracetic acid. External review draft (Dated:
March 2015).

[https://www.cdc.gov/niosh/docket/review/docket156a/pdfs/g1-013--peracetic-acid-cas-79-21-0.pdf].

Pechacek N, Osorio M, Caudill J, Peterson B [2015]. Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. Toxicology Letters 233: 45-57.

Dated: March 1, 2017.

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